

## REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

### **I. Introduction**

The specification has been amended to correct typographical errors, i.e., the particle size should be in the unit of “micrometer” rather than “mm.” The present application is a divisional application of U.S. Patent Application No. 08/948,216, now issued as U.S. Patent No. 6,264,922. The exemplary support for these amendments can be found in the specification of the parent ‘922 patent, for example, at column 14, lines 31-33, where it states that “[n]anoparticles of beclomethasone dipropionate in 2.5% polyvinyl alcohol had a particle size distribution of  $0.26 \pm 0.13$  *micrometer*,” and at column 15, lines 38-40, where it states that “[t]he nanoparticles have particles size distributions with 80% of the particles being less than 2.5 *micrometer*” (emphasis added).

Claims 1-27, 41 and 45-50 were cancelled previously. Claims 37-38 and 44 are cancelled in this response without prejudice or disclaimer thereof. Applicants reserve the right to pursue the subject matter of any cancelled claims in one or more continuing applications.

Claims 28-32, 42-43 and 51-59 have been amended. Claims 59-63 have been added. All these revisions find support in the original claims, and specification, for example, at page 2, lines 29-34, and page 3, lines 21-24.

Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 28-36, 39-40, 42-43, and 51-63 will be pending.

**II. Claim Objection**

The Examiner objected to claim 44 for a typographical error. Claim 44 is cancelled thereby mooting the objection.

**III. Rejection of Claims under 35 U.S.C. § 101**

Claims 42-43 are rejected under 35 U.S.C. § 101 for alleged improper process claims. Applicants respectfully traverse the rejection.

Claims 42 and 43 have been amended to recite the steps in the process. Therefore, Applicants respectfully request withdrawal of the rejection.

**IV. Rejection of Claims under 35 U.S.C. § 112, first paragraph**

**A. Alleged Lack of Written Description**

The rejection of claims 28-40, 42-45, and 47-59 under 35 U.S.C. § 112, first paragraph, for alleged lack of written description is maintained. Claims 37-38, 44-45 and 47-50 are cancelled thereby mooting the rejection of these claims. Applicants respectfully traverse the rejection of the remaining claims.

The Examiner acknowledges that the specification describes that the claimed invention “is particularly useful for the treatment of specific diseases (i.e., asthma, emphysema, respiratory distress syndrome, chronic bronchitis, cystic fibrosis, AIDS, and AIDS related pneumonia),” but alleges that “there is no mention of the specific required steps in the instant specification” and that “[the specification does] not describe a method of treating a specific disease by administration to a mammal’s lungs.” Office Action, page 4, lines 1-3, 4-5, and 8-9. Applicants respectfully disagree.

Claim 28 explicitly recites the steps of a method for treating a respiratory illness in a mammal, including (a) providing an aerosol composition and (b) administering the aerosol composition to the lungs of the mammal. These steps are supported by the specification, for example, in the paragraph bridging pages 2 and 3. Moreover, Example 2 provides a detailed description of administration of the formulation to a rabbit. *See* page 24, lines 9-14. Accordingly, the claims satisfy the written description requirement and the rejection should be withdrawn.

Moreover, the Examiner contends that the specification describes a particle size distribution of “ $0.26 \pm 0.13$  mm,” which “is several orders of magnitude greater than what is claimed” (Office Action, page 4, lines 5-11). As discussed above, Applicants have amended the specification to correct the typographical error. The particle size distribution should be “ $0.26 \pm 0.13$  micrometer,” which corresponds to  $260 \pm 130$  nm. Therefore, the specification provides ample written description for the claims.

The Examiner further asserts that the prior art did not recognize “crystallization of red blood cells, white blood cells, [and] blood plasma” (office action, page 4, lines 13-17). The rejection is moot in view of cancellation of claim 37, which recites “blood products and substitutes.”

**B. Alleged Lack of Enablement**

Claims 28-37, 39-40, 42-45 and 47-59 are rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Claims 37, 44-45 and 47-50 are cancelled thereby mooting the rejection of these claims. Applicants respectfully traverse the rejection of the remaining claims.

Specifically, the Examiner acknowledges that the specification is enabling for the treatment of a respiratory illness, such as asthma, cystic fibrosis, emphysema, chronic bronchitis, and respiratory distress syndrome by administration to the lungs of a mammal of an aqueous

suspension of crystalline beclomethasone, but does not reasonably provide enablement for the treatment of any respiratory disease with any drug.

Without acquiescing to the stated rationale for the rejection, Applicants choose to advance the prosecution by amending claim 28 to recite the specific illness and beclomethasone as the therapeutic agent. Therefore, Applicants respectfully request withdrawal of the rejection.

**V. Rejection of Claims under 35 U.S.C. § 112, second paragraph**

Claims 29-31 and 51-59 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for the recitation of the phrase “less than about.” The claims have been amended to recite “less than” and new claims 60-63 have been added to recite “about.”

Claim 32 is rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for its recitation of “polyoxyethylene castor oil derivatives.” The term “derivatives” has been deleted in the claim.

Claims 42-43 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite because they do not set forth the method steps. Claims 42-43 have been amended to recite the specific method steps.

Claim 37 is rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for its recitation of both antithyroid agents and thyroid agents. The rejection is moot in view of cancellation of the claim.

Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

**VI. Nonstatutory Obviousness-Type Double Patenting Rejection**

Claims 28-31, 33-49 and 51-59 are rejected on the ground of nonstatutory obviousness-type double patenting over claims 8 and 24-30 of U.S. Patent No. 6,264,922. Applicants respectfully traverse the rejection.

Applicants submitted a terminal disclaimer on February 4, 2004 and the Examiner explicitly acknowledged that “[d]ouble patenting rejection is withdrawn, because a terminal disclaimer has been filed and accepted” (Final Office Action issued on June 17, 2004, page 2, first paragraph). Therefore, Applicants respectfully request the Examiner clarify and withdraw the rejection in view of the terminal disclaimer on the record.

Claims 28-31, 33-49 and 51-59 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 5-7 of copending Application No. 11/592,262.

Because the rejection is provisional, Applicants choose to defer any action until the Examiner indicates that the claims are otherwise allowable.

**CONCLUSION**

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid

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amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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